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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,833	01/27/2004	Michal Ayalon-Soffer	27256	8418

7590

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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/764,833	AYALON-SOFFER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-207 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-207 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

***ELECTION/RESTRICTIONS***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**GROUPS**

- I. Claims 1-13, 16, 20-26, 29-32, 35, 39-45, 48-51, 54, 58-64, 67-70, 73, 77-83, 87-89, 92, 96-102, 105-108, 111, 115-121, 124-127, 130, 134-140, 143-146, 149, 153-159, 162-165, 168, 172-176, 179-182, 185, 189-195, 198-201, and 204, drawn to isolated polynucleotides, oligonucleotides, and nucleic acid constructs, classified in class 536, subclass 23.1. If this specie is elected, then the below summarized specie election is further required.
- II. Claims 14, 27, 28, 33, 46-47, 52, 65-66, 71, 84-85, 90, 103-104, 109, 122-123, 128, 141-142, 147, 160-161, 166, 177-178, 183, 196-197, and 202, drawn to isolated polypeptides, classified in class 530, subclass 300. If this specie is elected, then the below summarized specie election is further required.
- III. Claims 15, 34, 53, 72, 91, 110, 129, 148, 167, 184, and 203, drawn to an antibody or an antibody fragment, classified in class 424, subclass 130.1. If this specie is elected, then the below summarized specie election is further required.
- IV. Claims 17, 36, 55, 74, 93, 112, 131, 150, 169, 186, and 205, drawn to a pharmaceutical composition, classified in class 702, subclass 019. If this specie is elected, then the below summarized specie election is further required.
- V. Claims 18, 19, 37, 38, 56-57, 75-76, 94-95, 113-114, 132-133, 151-152, 170-171, 187-188, and 206-207 drawn to a method of treating disease in a subject, classified in class 514, subclass 2. If this specie is elected, then the below summarized specie election is further required.

The inventions are distinct and divergent, each from the other because of the following reasons:

The inventions of Groups I-IV are independent inventions because they are drawn to different chemical types regarding critical limitations therein. The critical feature of Group I is a polynucleotide. The critical feature of Group II is a polypeptide. The critical feature of Group III is an antibody. The critical feature of Group IV is a pharmaceutical compound. It is acknowledged that various processing steps may cause a polypeptide of Group II to be directed as to its synthesis by a polynucleotide of Group I, however the completely separate chemical types of the inventions of the polynucleotide and polypeptide Groups supports the undue search burden if both were examined together. Additionally, polypeptides, polynucleotides, antibodies, and pharmaceutical compounds have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to addition, subtractions, enzyme action, etc.

The inventions of Group II and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process as claimed can be practiced with another materially different product. For example, as Met-driven tumor growth depends on the

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availability and tissue distribution of active HGF, any HGF-antagonizing agent could be used in the treatment of Met-related pathologies [Cancer Research, 60, 768–773, 2000].

The inventions of Groups [I, III, and IV] and Group V are unrelated. None of the products of Groups I, III, and IV are limited to be used with the particular method of Group V. Thus, the search for these Groups I, II, III, IV, and V together would present an undue search burden as they are directed to methods, systems, and products that are generally distinct and separate.

Because these inventions are distinct and divergent for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### **SPECIE ELECTION REQUIREMENT**

If Specie V is elected, the applicant is further required to make the following specie elections for purposes of examination:

**Specie A:** Species of disease are cited in claims 18, 37, 56, 75, 94, 113, 132, 151, 170, 187, and 206, which are generally separately classified and published, and thus document undue search burden if searched together. Thus applicants are required to select one type of disease from those listed in claims 18, 37, 56, 75, 94, 113, 132, 151, 170, 187, and 206.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic to the above species.

**Sequence Election Requirement Applicable to All Groups**

In addition, each Group detailed above reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore a further restriction is applied to each Group. For an elected Group drawn to either amino acid or polypeptide sequences, the applicant must further elect a **single** amino acid or a **single** polypeptide sequence. (See MPEP 803.04). Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, the requirements of 37 CFR 1.141 et seq. are no longer waived and applicant is required to elect a single sequence for examination. Applicant is reminded that this is a restriction requirement, not an election of species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention and the SEQ ID number to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**MARJORIE A. MORAN**  
**PRIMARY EXAMINER**

*Marjorie A. Moran*  
1/19/06